

APR - 7 2000

EXHIBIT 2

Mikasa X-Ray Co., LTD. (Manufacturer) 13-2, Hongo 3-chome Bunkyo-Ku, Tokyo 113-0033 Japan Tel 81-3-3813-3911 Fax 81-3-3813-4420	MinXray, Inc (Initial Distributor) 3611 Commercial Ave. Northbrook, IL 60062 Tel 847-564-0323 Fax 847-564-9040 Contact: Keith Kretchmer
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January 7, 2000

510(k) Summary of Safety and Effectiveness

- Identification of the Device:**
Proprietary-Trade Name: "MinXray HF70D High Frequency Portable Dental X-Ray Unit"
Classification Name: Extraoral source x-ray system, Product Code EHD
Common/Usual Name: Portable Dental X-Ray
- Equivalent legally marketed devices** This product is similar in function to the MinXray P200D Mark III (a pre-amendments device)
- Indications for Use (intended use)** The HF70D is intended for use by a qualified/trained dentist or dental technician on both adult and pediatric subjects for taking diagnostic extraoral dental x-rays (intraoral image receptors).
- Description of the Device:** The HF70D is a portable unit which operates from 120 V 50-60~ AC. The unit utilizes a newly designed high frequency inverter and can be either mounted to a tripod or support arm or can be hand held. The usual safety precautions regarding the use of x-rays must be observed by the operator.
- Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart, HF70D

Characteristic	MinXray P200D Mark III	MinXray HF70D
Intended Use:	Extraoral dental x-ray source (intraoral image receptors)	SAME
Physical characteristics:		
Size/weight	Body 5"H x 8.5" W x 9.5" D Cone 2" Dia. x 6" L Weight 18 lbs.	Body 5.8" H x 4.8" W x 7.9" D Cone (SAME) Weight 10.4 lbs.
Energy Source:	120 v 50-60~ AC	SAME
User Interface	Rotary switch for exposure time selection	Up-Down pushbuttons for three kVp selections and exposure time selections with LED indicators
Exposure times	0.08-2 Sec. In 16 steps	0.02-1.98 Sec in 99 steps.
Ma.	12 ma	10 ma
KvP	63 KvP	60, 65, 70 KvP
Standards and Safety characteristics:		
Performance Standard	21 CFR 1020.30	SAME
Electrical safety:	UL-544, IEC 601	UL 2601, IEC 60601-1

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of MinXray that the "HF70D" is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Keith Kretchmer
President
MinXray, Inc.
3611 Commercial Avenue
Northbrook, IL 60062

Re: K000061
MinXray HF70D High Frequency Portable Dental
Xray Unit
Dated: January 7, 2000
Received: January 10, 2000
Regulatory Class: II
21 CFR 872.1800/Procode: 90 EHD

Dear Mr. Kretchmer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

j) Indications for Use

510(k) Number K 000061

Device Name: MinXray HF70D

Indications for Use: The HF70D is intended for use by a qualified/trained dentist or dental technician on both adult and pediatric subjects for taking diagnostic dental x-rays using intraoral image receptors.

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Korman
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K000061

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)